

The Protection of Human Subjects in Research

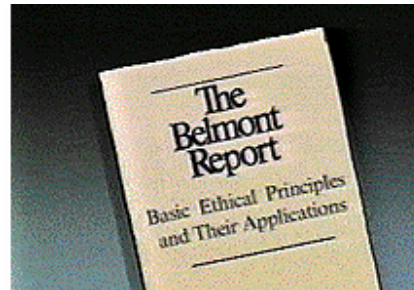
CARRA Peer Review Training
2005

History of Abuses

- Nuremburg Code (1947)
- Declaration of Helsinki (1964)
- Willowbrook (1960's)
- Jewish Chronic Disease Hospital (1960's)
- Tuskegee Syphilis Study - US Public Health Service (1932-1972)

The Belmont Report

Ethical Principles and Guidelines for the Protection of Human Subjects of Research



**The National Commission for the Protection of Human
Subjects of Biomedical and Behavioral Research**

April 18, 1979

The Belmont Report

Three Basic Ethical Principles:

- Respect for Persons
 - Individual autonomy
 - Protection of individuals with reduced autonomy
- Beneficence
 - Maximize benefits and minimize harms
- Justice
 - Equitable distribution of research costs and benefits

Human Subjects in Research

A human subject is a living individual about whom an investigator conducting research obtains

- data through intervention or interaction with the individual, or
- identifiable private information

Basic Protections for Human Subjects

- Institutional Assurance
- Institutional Review Board (IRB) Review
- Informed Consent

Institutional Assurance

Each institution “engaged” in human subject research conducted or supported by HHS must obtain an assurance of compliance approved by the Office for Human Research Protections.

Institutional Review Board (IRB)

A committee charged with the review of human subject research to assure that the subjects' rights and welfare are adequately protected.

Informed Consent

Informed consent is not a single event or just a form to be signed - rather, it is an educational process that takes place between the investigator and the prospective subject